Ethical issues in Patient Safety Research

Interpreting existing guidance

World Health Organization

Ethical issues in Patient Safety Research

Interpreting existing guidance

World Health Organization

WHO Library Cataloguing-in-Publication Data:

Ethical issues in patient safety research: interpreting existing guidance.

1. Patient safety. 2. Ethics, Research. 3. Ethical review. 4. Humans.
5. General practice – standards. 6. Medical errors – prevention and control.
I.World Health Organization.

ISBN 978 92 4 150547 5 (NLM classification: WX 185)

Design by CommonSense, Greece

Printed by the WHO document Production Services, Geneva, Switzerland.

Foreword

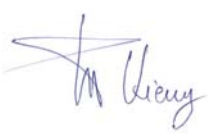
Research involving human participants must be conducted in a manner that respects the dignity, safety, and rights of research participants. This principle has formed the basis of ethically acceptable clinical and epidemiological research for decades. Research teams all over the world have increasingly recognized the need for external oversight in securing ethical advice, and independent ethics committees have been established to carry out this role. At the same time, significant scholarly work and international guidance have provided the philosophical and operational framework for improving the ethical conduct of research and building appropriate safeguards.

The recent expansion of research aiming to analyse the nature, behaviour and consequences of patient safety incidents and their surrounding circumstances, as well as the impact of innovative strategies to address patient safety problems, poses new research questions that raise new, and unresolved, ethical questions. For example, what does the ethical principle of "beneficence" require in studies that identify physician errors in on-going or recorded clinical practice? What does the principle of "respect for persons" require in studies that involve the observation of patients' and professionals' behaviour? When evaluating a strategy to reduce errors, is ethics committee review required when the only difference from usual practice is the collection of data to see if the strategy improves care? These and other challenges raised by patient safety research have been challenging ethics committees around the globe.

Tens of millions of patients worldwide suffer disabling injuries or death every year due to unsafe medical practices and care. As such, the World Health Organization (WHO) recognizes the ethical imperative to identify strategies that can improve the safety of patients as they receive care worldwide. In identifying ethical principles to guide this and other types of human research, WHO endorses the widely-used Council on International Organizations of Medical Sciences (CIOMS) "International Ethical Guidelines for Biomedical Research involving Human Subjects" (2002) and "International Ethical Guidelines for Epidemiological Research (2009)," and the World Medical Association (WMA) Declaration of Helsinki (2008). This report represents an important effort to apply the ethical guidance provided through these documents to the specific field of patient safety research. The report aims to help patient safety professionals, investigators, health-care institutions, ethics review committees, health authorities and others ensure the ethical conduct of patient safety activities. It synthesizes the organized deliberations of a highly respected group of research ethics and patient safety specialists from all over the world who, over the past years, have collaborated with WHO to produce this guidance. This document is especially important in resource-poor settings, where there is a pressing need to conduct more locally applicable research for health, including studies related to patient safety.

The guidance included in this report, is the first version of which we expect to be a continually maturing document. WHO, therefore, encourages readers and users of this document to provide feedback, allowing the continuous review and refinement of the guidance, based on additional input and new scholarly work.

This report represents the joint effort of the international experts who have provided their deliberations, together with the WHO Patient Safety Programme and the Secretariat of the WHO Ethics Review Committee, which steered and managed the process. I commend them all for taking on this important task.



Dr Marie-Paule Kieny
Assistant Director-General
Health Systems and Innovation
World Health Organization

Acknowledgements

The World Health Organization is grateful to all expert collaborators who contributed to the conception, design and execution of this report. Their names and affiliations as well as their main contribution are listed below.

Contributors at the International Expert Consultation on Ethical Issues for Patient Safety Research, May 2010

Gertrude Sika Avortri Ghana Health Service, Ghana
Anant Bhan Independent Researcher, Pune, India
Sarah Edwards University College London, UK
Samia Hurst Université de Genève, Switzerland
Janis Lazdins Independent Researcher, Switzerland
Mondher Letaief University Hospital of Monastir, Tunisia
Osnat Levtzion-Korach Assaf Harofeh Medical Center, Israel
Richard Lilford University of Birmingham, UK
Josephine Ocloo King's Patient Safety and Service Quality Research Centre, UK
Les Olson External Member of the WHO Ethics Review Committee

External Reviewers

Carlos Aibar Zaragoza University, Spain
Ross Baker University of Toronto, Canada
David Bates Brigham & Women's Hospital, USA
Anant Bhan Independent Researcher, India
Hans Van Delden University Medical Center, Utrecht, Netherlands, President, CIOMS
Susan Dovey University of Otago, New Zealand
Ruth Faden Johns Hopkins Berman Institute of Bioethics, USA
Sev Fluss Senior Advisor, CIOMS
Otmar Kloiber World Medical Association
Rieke Van der Graaf University Medical Center, Utrecht, Netherlands
George Liu La Trobe University, Australia
Philippe Michel University Hospital Lyon, France
William Runciman University of South Australia, Australia
Asavaroengchai Santawat King Chulalongkorn Memorial Hospital, Thailand
Claudia Travassos Fundaçao Oswaldo Cruz, Brazil
Michel Valloton University of Geneva, Switzerland, Former President, CIOMS
Douglas Wassenaar University of KwaZulu-Natal, South Africa
William Weeks The Dartmouth Institute, USA

Systematic Review of the literature

Danielle Whicher Johns Hopkins Bloomberg School of Public Health, USA
Kendra Harris Johns Hopkins School of Medicine, USA
Jonathan Knocke Mayo Clinic, USA

WHO Staff Contributors

Marie Charlotte Bouesseau Ethics and Social Determinants, WHO
Melba Gomes Tropical Disease Research, WHO & member of the WHO Ethics Review Committee
Brooke R Johnson Reproductive Health and Research, WHO & Chair of WHO Ethics Review Committee
Kwok-Cho Tang Chronic Disease and Health promotion, WHO & member of the WHO Ethics Review Committee
Sergio Nishioka Immunization Vaccines and Biologicals, WHO & member of the WHO Ethics Review Committee
Katthyana Aparicio WHO Patient Safety Programme
Mobasher Butt WHO Patient Safety Programme (currently in the National Health Service, UK)
Nittita Prasopa-Plaizier WHO Patient Safety Programme

Drafting & Steering Group

Nancy Kass WHO Research Policy & Cooperation (currently at Johns Hopkins Bloomberg School of Public Health, USA)
Carl Coleman Independent Ethics Consultant
Carmen Audera-Lopez WHO Patient Safety Programme
Abha Saxena Ethics and Social Determinants, WHO, and Secretary of the WHO Ethics Review Committee
Itziar Larizgoitia WHO Patient Safety Programme

Table of contents

1. Introduction

This report responds to a request from patient safety researchers and research ethics committees (REC) for advice on how to interpret existing research ethics guidelines in the context of patient safety research. The report, which was produced by the WHO Patient Safety Programme and the WHO ERC Secretariat, builds on the reflections of an international expert group and was further enhanced by internal and external expert reviews by research ethics specialists and patient safety and quality improvement scientists from across the world. As explained in the foreword, this is the first version of this report, which will be revised to include future input, as evidence and scholarship in the area of patient safety research evolve.

This document is not intended to establish any new ethical principles. Rather, it represents an interpretation and application of existing, internationally accepted ethical principles to specific questions that arise in the context of patient safety activities. It is designed to be useful to patient safety professionals, investigators, health-care institutions, ethics review committees, health authorities and others aiming to ensure ethical conduct of patient safety research activities. It is hoped that the document will increase the attention given to ethical issues around patient safety research around the world, but particularly in the burden of unsafe care in developing countries, where the risk of harm to patients is likely to be greater, due to limitations in infrastructure, technologies, and human resources.[3] A retrospective analysis of medical records of patients admitted to 26 hospitals in eight developing and transitional countries estimated an incidence of preventable harm of almost 1 in 10.[4,5]

Research to understand the causes of unsafe care and to identify potential solutions involves diverse scientific designs and methodologies. For example, research may be based on a review of medical records, observations, surveys or interviews. It may use controlled randomized designs, allocating different hospitals or clinical units to alternative ways of delivering care, or it may use simulations. While patient safety studies share methodologies with many other types of health-related research, some aspects of patient safety research may appear different in ways that can have a bearing on the types and extent of ethical oversight that may be warranted.[6] For example, in patient safety research, the research "subject" who is targeted with a new intervention may be a health-care provider rather than a patient, even when outcomes are based on patient-related information, or the target may be a "system" of care rather than an individual. The issues raised